APR - 3 2003

Quantimetrix Corporation
2005 Manhattan Beach Boulevard
Redondo Beach, CA 90278-1205

TEL (800) 624-8380 or (310) 536-0006
FAX (800) 845-1834 or (310) 536-9977

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

The assigned 510(k) number is: K030826

Proprietary Name:	Preciset® DAT Amphetamine
Common Name:	Calibrators/Controls
Classification Name:	Calibrators, Drug Mixture
Medical specialty:	Clinical Toxicology
Product Code:	DKB
Device class:	2
Regulation No:	862.3200
Manufacturer:	Quantimetrix Corporation 2005 Manhattan Beach Boulevard Redondo Beach CA 90278 Phone: 310/536-0006 FAX: 310/536-9977
Contact Persons:	Gebhard Neyer, Ph.D., Director of R&D, 310-536-0006
Registration No:	2020715

The Quantimetrix Preciset® DAT Amphetamine drug of abuse calibrator and controls are supplied liquid in a glass bottle. They consist of drug-free human urine to which preservative, stabilizer and drug analyte have been added to achieve distinctive levels. The drug added is:
d-amphetamine

Drug concentration is determined using GC/MS.
The Quantimetrix calibrator is substantially equivalent to the currently marketed **Emit®**

Calibrators/controls manufactured by **Syva Company.**
Both feature similar matrices, constituents and stability claims.

Intended Use

The Preciset DAT Amphetamine calibrators are designed for the calibration of the Roche Abuscreen® OnLine assays for Amphetamines and the cassette COBAS INTEGRA® Amphetamines (AMPS) for the determination of amphetamines in human urine on automated clinical chemistry analyzers.

Performance Characteristics

Accelerated stability studies (25°C and 37°C) and real time studies were performed to validate the shelf life claim and the opened vial claim of the calibrators/controls.
When tested with the Roche immunoassays (currently under development) the calibrators were found to perform well and to be sufficiently stable for their intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR - 3 2003

Gebhard Neyer, Ph.D.
Director, Research & Development
Quantimetrix Corporation
2005 Manhattan Beach Boulevard
Redondo Beach, CA 90278

Re: k030826
Trade/Device Name: Preciset® DAT Amphetamine
Regulation Number: 21 CFR 862.3200
Regulation Name: Clinical toxicology calibrator
Regulatory Class: Class II
Product Code: DIJ
Dated: March 3, 2003
Received: March 14, 2003

Dear Dr. Neyer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K030826

Device Name: Preciset® DAT Amphetamine

Drug of Abuse Calibrators/Controls

Indications For Use:

The Preciset DAT Amphetamine calibrators are designed for the calibration of the Roche Abuscreen® OnLine assays for Amphetamines and the cassette COBAS INTEGRA® Amphetamines (AMPS) for the determination of amphetamines in human urine on automated clinical chemistry analyzers.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K030826

Prescription Use ✓ OR **Over-The-Counter Use**_____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)